Biotech Business Lessons
for Defense Acquisition

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Abstract

The desire to innovate and transform defense acquisition is ill-informed regarding the true meaning of innovation and transformation. The Department of Defense (DOD) would be best served by radical modifications driven by a capitalist market approach to freedom and accountability. A fruitful shift in DOD weapons acquisitions would embrace concepts from the biotech industry—such as being science-based and open to innovative applications of technology—and implement required changes in doctrine and organization. While the need for reform is obvious, the will to reform is less evident. However, examples and lessons from private business sectors would serve DOD interests well.

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Acquisition reform! No other two words so stress or trouble acquisition professionals—other than perhaps *program cancellation*. The latter is so seldom uttered, and even less-often actualized, that its significance is effectively removed from the defense acquisition lexicon. Indeed the two words that create the most anxiety inside both the government acquisition community and their defense contractor counterparts is *acquisition reform*.

Granted, the history of acquisition reform is replete with unfinished and/or unsuccessful reform efforts.[1] During the last half century, reform efforts have rarely changed the status quo and even more rarely fixed any protracted shortcoming of weapons systems acquisition or removed barriers. Since the 1960s saw the first calls for reform, little real change has made acquisition jobs easier, more efficient or effective, or demonstrably faster. Possibly the most notable example was technology executive David Packard's departure from the DOD, where he briefly served as a

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deputy secretary, following unrealized reforms in the early 1970s.[2] Most notably, "fly before buy," a reform plan aimed at developing prototypes and competition between contractors prior to awarding defense contracts and entering production of new systems, did not endure. Underlying incentives of both the DOD program managers and defense contractors remain unchanged, and the division of labor balance between the services and the Office of the Secretary of Defense (OSD) remains dysfunctional, with duplicative tasks and decision authorities. The typical change has been to add more oversight, more work, and more time to accomplish the same task. A few things are certain: (1) the amount of documentation has greatly increased; (2) the influence of non–decision makers has proliferated; (3) unity of command on major defense acquisition programs is nonexistent; and, perhaps most critical, (4) there is a shrinking competitive defense industry. Today acquisition reform is yet again attracting considerable attention within the DOD and Congress. The current budget environment and the inability of previous reform efforts to gain traction or produce desired results precipitate another attempt at improvements. Can we treat DOD acquisition as a therapeutic area addressable through lessons from industry—particularly biotech business approaches? The answer is, "Yes." This article first discusses some of the problems with the current DOD acquisition process. Next, it uses Amgen, Inc. as a case study of lessons to be learned from the biotech industry. It concludes with recommendations for DOD exploitation.

Current DOD Acquisition Problems

The acquisition process is awash with subtleties that allow influence and direction on how to design and accomplish strategies and tasks leading to milestone decisions. Absent unity of command, various stakeholders influence program managers and sway priorities within programs.[3] The large number of associated subprocesses opens the door for direction and coercion that hinders efficient and effective completion. Further exacerbating the DOD's problems is a massive oversight structure. This complex structure consists of statutes, circulars, regulations, directives, instructions, policies, rules, standard operating procedures, cultural expectations, ways of doing business, and stakeholder interests—all of which burden the acquisition process and remove the authority of program managers while diluting accountability.[4] It also contains hundreds of processes, flows, meetings, and approvals required to move an acquisi-

tion program through DOD requirements, across hurdles, and eventually to a decision maker. All the while, various stakeholders and influence peddlers impose extra requirements or alternating acquisition strategies.

While the acquisition regulations (DOD 5000-series of documents) are pending revision, one can expect little change. Whether reissued as a directive or an instruction and regardless of the 5000's provisions, the processes and methods are so firmly ingrained that change will be slow, superficial, or absent altogether. If by some chance the new series is permissive of real tactical and operational change, institutional and bureaucratic inertia will stymie those provisions. Within a bureaucracy, absent a new proscribed process, the old one will prevail because, as organizational management expert Peter Drucker is purported to have quipped, "Culture eats change for breakfast."

The prevailing and persistent inertial tendencies within the DOD bureaucracy are composed of a multitude of personnel, within the services and OSD, whose positions exist to perform checks and oversight. However, redundancy exists in oversight, which often undoes, redoes, and second-guesses service decisions, creating work, rework, and a copious amount of wasted activity throughout the processes.[5] Such oversight and redundancy slows programs and adds millions to their costs. At the levels of the services and the OSD, much of the oversight is inherently not value-added and usually serves to stymie decisions already made by more senior personnel and those closer to the program. In fact, the OSD increasingly usurps the services ability to manage programs. Removing OSD redundancies and control would allow the services to better address their particular needs. Service-based control without such pervasive OSD interference frees the services to better tailor programs, coupled with and reflective of specific mission needs.[6] The recent call to tailor program requirements is destined to fail unless continued functional area demands for non–value-added processes are denied.[7] However, permission to tailor program requirements, obtaining concessions from specific functional processes, is unlikely to be granted. Admission that particular processes or actions are tailorable repudiates what functional personnel hold dear—that their hurdles are vital to some moral or ethical responsibility to protect or safeguard. Unfortunately, in the collective minds of the functionals, acquiescence to any tailoring undermines uniform application of procedures and threatens the creditability of the functionals' positions. Moreover, a tailored process becomes pre-

cedence for additional requests. The functional is undermined and its personnel exposed as being without meaningful work—billets vulnerable to poaching or deletion. Stripping a bureaucracy of its layers is very difficult. Overhead and bureaucracy is overly populated by petty tyrants that slow and thwart accomplishments. These maintain an outsized role relative to their value creation. The bureaucracy will fight to preserve itself, for example the jobs of the staffs that fabricate import in their roles.

Other problematic issues are the low percentages defense firms reinvest in research and development (R&D) and the way defense R&D currently operates. The DOD's R&D funding mechanisms, driving top-down strategic plans often disconnected from capabilities and technologies, block the innovation the DOD seeks. The existing defense establishment's planning process fundamentally limits the way innovation currently gets inserted. Therefore, already realized ideas and technologies are built into the five-year plan and subsequently put into decades-long programs of record. This creates two deleterious effects. As a first consequence, it locks ideas into long program schedules, which results in delayed technology insertion—sometimes long after commercial obsolescence.

A second concern is the barrier to entry that this method of R&D funding has with respect to small innovative companies joining the defense acquisition community. The DOD's small business provisions notwithstanding, innovation has a difficult time breaking through to the defense business. Small businesses possessing disruptive, creative, or simply value-enhancing innovation experience immense difficulties entering the defense marketplace. Often the path to entrance is to sell the idea or be subsumed by an existing large defense contractor, thus enabling and perpetuating the previously cited deleterious effects. Small business difficulties aside, many innovative departures from established value chains are the products of large businesses—a growing number of which choose not to do business with the DOD, for examples 3M and Apple (neither of which are defense contractors). These latter firms consciously choose not to participate in the defense acquisition community because of the DOD's value-destroying process requirements, reporting requirements, and intrusive management, while innovative newcomers are blocked by the DOD's R&D methodology and its virtually impenetrable layers of bureaucracy.

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Lessons from Biotech

Over the past two decades, personal conversations with numerous program managers, several system program office directors, and program executive officers regarding the perception of acquisition reform have often wound down with a familiar refrain. Following the suggestion to incorporate business ideas to reform various aspects of the weapons acquisition processes, the histogram of responses produced one clear quip that overwhelmingly constitutes the mode: "We deal in life and death; if business gets it wrong nobody dies. If we get it wrong, people die." The implication is that the DOD cannot apply innovation and efficient methods from private industry sectors to major defense acquisition. Until now there was little to counter that argument, and it thwarted further advocacy for business methods. However examining the case of Amgen, a very innovative private-sector biotechnology company, an enlightened argument emerges. In drug development, if a firm gets clinical trials wrong, more than a pilot, tank crew, or special operations team might die; thousands or tens of thousands of people could be affected—along with the survival of the company. While not the only biotech firm in the United States, Amgen is the industry leader not only in market share and revenue but also in the robustness of its R&D pipeline in a growth industry. Amgen serves as a logical model for DOD innovation and acquisition approaches. Applying broad innovation and information technology (IT) from the biotech industry and other private-sector applications can move the DOD toward a new era of productivity and respectability in several ways, including economic processes, science and technology to drive results, and R&D funding. However, this move requires bold, brave, and, at times, outspoken leadership.

One observation is the disparity between the DOD and Amgen, with respect to detailed microeconomic business processes as well as broader operational and strategic decision making. The biotech industry is using proven cutting-edge technologies to rapidly advance their business and, more importantly, improve the lives of patients. The differences between the Amgen approaches and DOD acquisitions are striking. The speed of incorporation and the willingness to accept and act on change are glaring differences, with the advantage going to the private sector. In 2014 Amgen embarked on the Reaching Amgen's Full Potential program—composed of a number of initiatives designed to propel the company forward over the next 10 years. The radical difference in the concep-

tualization of this program versus DOD reform efforts is the underlying notion of facing the brutal facts confronting the company and the industry over the next few years as opposed to the DOD approach of always putting the solution in the out years.[8]

Similarly, the undersecretary of defense for acquisition, technology, and logistics (USD [AT&L]) has said, "We need to face the truth in this business."[9] Facing the brutal economic facts, Amgen is confronting pending expiration of patent protection on two major drug products, the advent of biosimilars, and the continual competition from traditional chemical-based drugs. A DOD analogy is the growth of antiaccess/area denial capabilities and the narrowing of the technology gap between the United States and its potential enemies. Amgen has taken an aggressive approach to leverage technology and push for needed changes to the industry that not only benefits its bottom line but most prominently improves patients' lives and supports the industry as a whole. The DOD has yet to act, merely adding to requirements rather than displacing lower-risk areas. As the outcome for the customer is of primary concern at Amgen, considerable attention is devoted to aligning business strategy to customer needs. On the contrary, the defense acquisition community continues to pursue all possible strategies. The DOD is bogged-down in the "shots on goal" mentality, pursuing every opportunity it can partially fund at a buy-in budget level—thus, inefficiently consuming resources and starving the most promising winners.

The Amgen example shows the crucial and valuable nature of a chief executive officer's (CEO) attention to initiatives.[10] However, even more decisive is the nature of the initiatives themselves. After 24 months, the company still was not talking about organizational box shuffling. Acknowledging that the process will be a three- to five-year effort, the understanding is that organizational modification will be an outcome, not a driver of change. Innovation and technology will change the approach. Offices will not simply be renamed to indicate reform. New ways of doing business are incorporated into existing business areas or functions.

At the forefront is the adoption of proven technology to drive results. Not the least of which is initial "manufacturing of the future" techniques that leverage technology to produce successful drug batches 9 percent more often than the industry norm. This particular technique, using continuous monitoring and real-time deviation notification, serves to reduce costs of goods manufactured and to increase productivity (drug

production). Another technology being leveraged to reduce capital costs is the implementation of newly developed disposable plastic bioreactors to replace room-sized operations that require cleaning between batches and best serve one volume of production. The new plastic bioreactors reduce turnover time between batches and allow for simultaneous production of multiple products, yielding increased production in the same space.

For Amgen, several ongoing and new projects leveraged innovative applications of analytical methods. From analytics applied to hard science to physician education to contract maximization, Amgen applied technology and new methods to large and rich datasets to innovate across the business—creating value. Conferring with leading firms from other industries, analytics produced new opportunities for sector growth, profit increases, and enlarged marketplace exposure. One key observation was the distinction between analysis and analytics. The former provides prospective on accomplishments; the latter informs relative to leveraging multidisciplinary and cross-industry possibilities to drive the future.

Beyond the significant cost reductions and quality increases produced by manufacturing process technology insertion, changes are occurring in the R&D domain as well. The notion of working *with* the Food and Drug Administration (FDA), rather than being confrontational, is serving to trim the time it takes to progress from drug discovery to patient access.[11] Among Amgen's initiatives is the desire to reduce the time between molecule discovery and commercialization from 15 to 10 years. Any reduction in this timeline will save billions of dollars across the research, translational sciences, development, clinical trials, and commercialization activities—savings that reduce the cost of and speed of access to both lifesaving and life-affirming treatments.

One such success was realized on a recent effort to forego traditional clinical trials in favor of virtual ones. Granted, this was not a drug product but a software model to provide predictive modeling for personalized medicine. Amgen sought and received initial approval to develop the "device" using virtual trials, which will save millions of dollars and speed this treatment tool to health-care providers years earlier than under the traditional approach. The FDA is looking for ways to quicken the pace of new treatment methods and tools. Working collaboratively, rather than antagonistically, opens opportunities to produce real results.

Coupling drug commercialization with device delivery methods as an integrated product is another way to leverage technology. The future

of biologic drug treatments contains more self-injected methods with embedded monitoring and wearable signaling technologies to increase treatment efficacy. By continually leveraging new technology and employing existing technologies from other industries, biotech and pharmaceutical companies produce not just incremental improvements for patients but also radical and revolutionary new treatments. This activity is the innovation that eventually produces transformative change. Said another way, innovation is value creating, and it begins with R&D.

In the multibillion dollar biotech and pharmaceutical sectors, R&D is an integral requirement to be part of the industry. The FDA does not contract with drug companies to develop treatments and cures aimed at specific health needs, funding research and making progress payments as products move through clinical trials. The companies themselves must invest in R&D from their revenue streams. The biotech and pharmaceuticals sectors invest in excess of 20 percent of their annual revenue into development of their future product pipelines. In fact, the US IT sector has an even higher percentage for R&D; and practically every industrial sector's R&D exceeds that of aerospace and defense. The US aerospace and defense industrial sector spends 3 percent on internal R&D.[12]

Complementing Amgen's technology strategy to improve drug development and manufacturing has been a shift in fundamental drug-development doctrine. Previously, the biotech industry as a whole focused on shots on goal. This mantra existed from the industry's emergence in the late 1970s until recently. The idea was to put money into as many promising therapeutic areas as possible. This approach can be likened to the proliferation of defense acquisition programs, some of marginal benefit; however, the volume of shots on goal absorbs resources from clear priorities.

Recently, the shift has been away from the shots-on-goal approach toward a "pick the winner" paradigm, looking across the therapeutic area research and the pipeline of possibilities to pick the molecule most likely to succeed and investing heavily in that one. This move is a further narrowing of the biotech business model within the area of human therapeutics. Early biotech firms, Amgen included, not only focused on human biologics but also on plant and animal biology for a variety of outcomes.

The pick-a-winner approach is focused on particular areas of research. Within the DOD, the Defense Advanced Research Projects Agency (DARPA) has this mission. However, the DOD has a poor track record and continues to fail more often than it succeeds in translating basic research to applied aspects across what is referred to as the *valley of death*, "the difficulty of covering the negative cash flow in the early stages of a startup, before their new product or service is bringing in revenue from real customers."[13] The biotech industry has better processes for translational science, allowing potential treatments to survive this kill zone. The short-term nature of DARPA projects and its raw research nature, while interesting, are usually not tied to the applications within existing or anticipated acquisition programs of record. The largest culprit in the DOD's failures to bring innovation across the valley of death is typically funding. It is symptomatic of a disconnect between the research agency and the program office in how to apply basic research, if any application is pursued at all. In the private sector, such research is closely tied to corporate goals and aims—in biotech to targetable drug products.

Another way biotech R&D is different from that sponsored by the DOD is the science-based nature of the business. In biotech it is widely accepted that "science makes money"—whether high science or low science, does not matter, as long as it helps patients and makes money.[14] Too often in the defense industry a misguided, contrary notion that money makes science prevails—thus, producing billion dollar efforts to "bend the laws of physics" and produce program results before the science is there. Often DOD expenditures prove nonproductive, with the breakthrough and eventual solution coming from outside the program or even external to the DOD. In the biotech industry, firms follow the science.[15] When the science fails to proceed, the lessons are documented, shared, and then applied wherever applicable to other related targets. The deadend is not bombarded with funds to break through the science. In fact, the notion of failing fast is rewarded. In biotechnology, you want to either succeed quickly or fail fast.[16] Indeed, "failure is regarded as part of the process."[17] Early realization and pronouncement—confession— of impracticality or impossibility saves millions of dollars and allows for quick refocusing to other potentialities. Both the personnel that succeed fast and those who help in fast-failure are sought out by others encountering emerging issues. Their insight and experiential wisdom is valued. The goal is to quickly reach a decision on feasibility and producibil-

ity. Those who save years and millions by clarifying difficulties and/or exposing impossibilities early are considered valuable assets and prized within the firm. They are leveraged to better pick the winners.

Unlike the DOD in the acquisition process, the FDA provides a binary decision at the milestone review point—not continuous involvement inside clinical trials. This is radically different from DOD processes, which have numerous, if not all, stakeholders involved throughout the acquisition process. The amount of time the FDA is actually engaged is minimal. The approach methodology and strategy is up to the company; the FDA simply confers approval or disapproval, based on what the company demonstrates. In between FDA decision reviews is autonomous time where drug companies are engaged in value-added activities. During this time, the FDA is not engaged, not receiving briefings, not requiring reports, not inserting requirements, not providing ideas or asking "what ifs." Juxtapose the FDA approach, leveraging free enterprise methods, against that of the DOD, creating conditions for centralized decision making. Granted, there are consultation and direction meetings with the FDA. However, these are typically held at the request of companies, not the FDA, and serve to elicit the FDA or gain insights on novel or innovative approaches.

Recommendations: Exploiting a Capitalist Market Approach

To the detriment of weapons-systems research, development, test, and production, market forces simply do not operate in the defense industry. A truly market-driven economy can greatly inform proposed changes and radically improve defense processes, talent management, and output realization. This view is not acquisition reform as seen before; market function requires real change, not reform of existing mechanisms. Thus, a revolution is needed—not evolution. Agility and innovation create disruptive change, often drastically altering the status quo. Unfortunately, previous DOD reform efforts were more akin to machinations superimposed on existing defense acquisition processes and structures.

Therefore, the DOD must revolutionize the process, not merely swing the pendulum. Since establishing the current structure during the McNamara era, the four or five large-scale reforms have failed. Sadly, defense professionals still live and operate in the McNamara era. The processes used today are merely broader and fatter versions of what was developed in the 1950s and inserted into the DOD in the 1960s.

Given that the defense acquisition community is the world's largest socialist economy, we must come to understand that, "Minor adjustments and corrections to the present acquisition process simply will not accomplish this vital job."[18] We should not obsess over the large aspect of this characterization of the defense establishment. The point is to recognize and comprehend the socialistic nature of the defense community. To that end, we must realize that the laws, policies, and regulations Congress and the DOD have promulgated are based on the assumption that the defense community is a free-enterprise system governed by competition.[19] To any attentive observer, this assumption is incorrect, *prima facie*. At best, the defense marketplace is a duopolistic monopsony, an environment where there are two suppliers and one buyer with dogmatic rigidity and no strategic economic approach.

In reality, we more often have one supplier for major defense end items. The strategic macroeconomics require us to understand that many defense firms operate and act—to some significant extent—like autonomous agencies of the government.[20] Major defense firms, with the notable exception of one, do not operate in the private, commercial sector of the economy.[21] The defense contractors are more akin to wholly-owned subsidiaries or autonomous agencies of the federal government.

The DOD and Congress must partner to abandon the current governing structure and adopt one that promotes the function of a capitalist market in weapons acquisition. This imperative represents a giant doctrinal shift. One big lesson from biotechnology specifically, and of a market economy more generally, is that the outcome of science + the market exceeds that of bureaucracy + federal funding (science + market > bureaucracy + tax dollars).[22] The forces that drive behavior and the nature of decision making are radically different in the market, and these differences serve to vector companies toward innovation and value creation.[23] Capitalist incentives drive down costs, reduce schedules, and improve performance. Further, the socialist nature of funded R&D and progress payments belie market mechanisms.

A strategic reorientation toward a free market would require defense firms operate and focus on value creation. Such a focus would force defense firms to iterate through value propositions and offer incremental upgrades to systems. If R&D were required via the private-sector model, the change would likely result in fewer funded programs that produce intensely determined research to add radically new or meaningful in-

cremental value. The free-enterprise method also solves another problem of centralized planning. Bureaucrats are not technologists and are completely unfamiliar with the science of emerging opportunities, lack technical depth regarding core technologies, and are ill-equipped to predict the next big leap forward. A top-down, directive approach does not create value or discover new ideas; clever people, properly incentivized, do. The point is—defense firms should fund their own R&D and bring products to market faster, with iterative innovative value, if not radically revolutionizing an approach. Prevailing defense acquisition conditions deliver neither timely technology, appropriate innovation, nor the potentiality of value. Significant change is needed, and to realize such, the DOD must implement radical previously "inconsiderable" alterations. Foremost, among these initiatives is, shed the morass of rules, procedures, policies, laws, and accepted ways of doing things. To be successful, the DOD must establish a framework of policies and approaches that allows the market to work.

From exposure to drug discovery and development, one obvious direction for defense acquisition reform is to remove the proscriptive nature of oversight, with all its required reviews and intrusive micromanagement of how tasks are approached and accomplished. A radical leap forward would be to mimic the drug approval process. The FDA does not dictate or instruct how a firm will reach the decision points associated with clinical trials. The decision points are hurdles that must be cleared via demonstration that criteria are met.

Sure, there are rules and lots of compliance, but drug companies are far freer to determine how to show safety and efficacy. The FDA establishes hurdle criteria, not continuous monitoring and proscriptive actions throughout the phases. Drug companies determine how to show safety and efficacy; then the FDA evaluates and renders judgment. Imagine the possibilities if defense program managers were left alone to develop programs and show performance at milestone reviews for approval or disapproval. Many people know what needs to be done, as studied evaluations have repeatedly pointed the way toward meaningful reforms, but lack of will, acquisition competence, or proper situational catalysts remain absent.[24] Without precedence, the current national fiscal crisis should be a catalyst and a long-standing one.[25] No amount of wishful thinking by the services or the DOD will remove the downward pressure on budgets; so a serious, radical shake-up of the process is ab-

solutely essential. Laws must be changed, accountability imposed, and program managers liberated to execute programs.

Implementing private-sector incentives is more than telling defense leaders to "operate more like a business"—a phrase that borders on laughable, given that few defense leaders or members of Congress have ever operated or functioned in a competitive business environment. Further, simply demanding results will not guarantee them, especially without realistic understandings of the environment and sound application of market principles. Fortunately, the private-business arena is replete with models and examples for improving the defense marketplace. The challenge for the DOD is to learn and accept those examples. We must also face the possibility that the DOD does not possess sufficient quantities of market-informed leadership and must seek such leadership externally. The barriers to business people serving tours in the DOD must be evaluated. It needs to leverage business experience as it did in the Second World War; lacking it internally, we must embrace exogenous sources. Private-sector firms readily employ cross-industry personnel to leverage R&D, process, and manufacturing knowledge for new applications and technology acceleration as a best practice. The DOD should do the same.

Transformation

Much of recent reform hinged around the idea of transformation and transformative initiatives.[26] Unfortunately, transformation is not something one drives within a defined temporal space. Rather, it is the combination of several factors that receive recognition upon reflection. Nothing suggests that transformation is a completely passive happenstance; actions to shepherd events are possible. However, the key ingredient in a transformative period is technological change, which is difficult, if not impossible, to invent or schedule.[27] Transformation contains three components: (1) technological change, (2) doctrinal change, and (3) organizational change.[28] While difficult to create all three components simultaneously on a programmed schedule, efforts can be made to observe and orient around ongoing changes and build synergies where possible.[29] Thus, leveraging technological developments appears critical to making valuable changes. Specifically, those changes that orchestrate both organizational and doctrinal moves to propagate, rather than ig-

nore or thwart, inclusion of advancing technology to realize successes—defined by peer leadership and/or market share.

What if the rest of the world did acquisition and infusion of technology the same way as the DOD? Imagine the state of computing capabilities if the IT industry took the same approach. Rather than continuous incremental updates via model improvements, what if the IT industry opted for revolutionary changes in 30-year chunks? The first personal computers would not have been commercialized but incorporated into a decades-long R&D effort to ultimately arrive at integrated phone/computing devices, denying the customer any value in the interim.

Large, complex, and expensive aspirations typically underperform relative to simpler, less-expensive alternatives.[30] Systematic progressions in capability and capacity should be preferred to revolutionary desires, decades in their attainment. The scientifically possible rather than by the bureaucratically imaginable should fuel the driving forces of the DOD acquisition process.[31] Weapons-systems acquisitions should be science-based and produce value-adding increments on a time horizon that feeds users' needs for increased capability. However, the established practice of funding major programs is to excite the bureaucracy, creating a situation where the possible matters less than the desired.[32] While a few Strategic Defense Initiative (SDI), Star Wars–like initiatives, might be worthy of pursuit, a whole portfolio of such technology-stretching programs is ill-advised and unproductive relative to war fighters' needs. By the time a system is fielded, it is already obsolete, and while in development the system likely consumed immoderate resources. Such large long-term strides do not maintain technological currency and are not consistent with free-enterprise business practices. Hence, there is no evidence of such projects at Amgen. Remember: succeed or fail—*fast*.

Unfortunately, the reality of multidecade program development—now followed by more decades of production—applies to far too many defense programs, of which we have too many, and contributes to a persistent inability to meet the expectations of cost, schedule, and performance. The fast and simple upgrade (iterating through versions to the next generation of capability) is much less glamorous but delivers timely, functional, and valuable solutions to the user. Additionally, studies show that the costs of separate, competing, incremental improvements are consistently less than the ultimate price tag of a large revolutionary program.[33] Therefore, prudence suggests that the lessons of private industry are worthy of

incorporation into, if not outright replacement of, the DOD's acquisition approaches. Some argue evolution precludes revolution, but evolution in a market-oriented manner creates the conditions for revolution, just as the car replaced the buggy; the mobile phone supplanted Ma Bell; and petroleum displaced whale oil. Revolution is more likely in such an environment than the current monopoly/duopoly situation sanctioned by a government or department unwilling or unable to deviate.

Areas to Exploit

What can the DOD acquisition community do in the areas of technology, doctrine, and organization to usher in real transformative or innovative impacts?[34] Under the heading of technology, the possibilities are broad, but first the DOD must incorporate technology faster. The length of DOD development programs, striving for large-block revolutionary jumps, creates diminishing manufacturing sources that further delay and complicate production and sustainability in the field. This approach to technology overly complicates programs of record and invites gold-plating of all aspects of weapons systems where each stakeholder must insert their update because there is only one chance in a decade, and as such, requirements creep becomes a serious problem to system completion.

The pick-a-winner approach applied to DOD acquisition would prioritize not only requirements but also programs, based on progress and milestone success. The budget would be allocated across programs based on likely—not optimistic—costs, using analytics to predict financial outcomes rather than program managers being incentivized to go with the lowest number in the estimated range of costs. This approach produces a shortened list of acquisition programs with a greater chance of timely completion, for example resources proportional to requirements or vice versa.

Additionally, the use of analytical methods (analytics) is underutilized. Some are as simple as earned value management (EVM). This simple quantitative evaluation of weapon systems progress is much maligned, despite its validated ability to predict acquisition delays and cost problems. Rather than embrace EVM analysis, many program managers throughout the DOD attempt to discredit EVM insights and refuse to incorporate them into their decision making or undermine the system by constantly changing the baseline against which measurement occurs.

From simple parametric methods to more complex simulation results, technology needs recognition in the DOD as not just data but as information. This change requires a significant quantity of personnel with the analytical aptitudes to convert data into information and effectively communicate information as knowledge.

One of the most-critically valuable changes available to the DOD is to leverage non-rebaselined, EVM-produced information into automatic program decisions. Such a change in doctrine could impose a "kill switch" for programs that exceed the range of recoverability as defined by EVM research on DOD acquisition experiences. This automatic kill-switch would terminate the program and force it to restart as a new request within the acquisition process. While some may argue such a kill-switch is the purpose of the Nunn–McCurdy amendment, this is not the case. Nunn–McCurdy simply requires reporting to Congress and permits rebaselining.[35] Based on Amgen's experience and other empirical knowledge, the tracking and association of project scope and cost is not beyond available capabilities. Maintaining properly scaled and scoped baselines is critical to understanding project performance and projected profitability (or lethality, in DOD parlance).[36] Unadulterated EVM data produces decision-quality information. However, in the absence of quality, unbiased decisions, the time has come for an automatic, analytically-driven kill-switch for programs in unrecoverable financial or schedule situations. Changing doctrine to use technology in this manner is a simple but effective use of analytics and could quickly be extended to unfavorable results from modeling and simulation technologies.

Other key changes in philosophy revolve around firm technology baselines, clearly understood software maturity measurements, and budget stability. The notion of concurrency has been somewhat discredited by the F-35 Joint Strike Fighter experience, as highlighted by USD (AT&L) Frank Kendall's reference to it as "acquisition malpractice."[37] Even though the fighter failed previously, it returned as a major acquisition program.[38] We need to firmly protect the notion of clearly defined and firmly adhered to requirements and the meaning of software maturity, informed by testing throughout the component coding and integration processes.[39] This concept is especially important since software comprises an ever-larger percentage of program components.

Moving to a framework focused on attributes of rapid delivery of "affordable systems that are available when needed and effective when

used" requires a culture change.[40] This is a doctrinal issue, in which the DOD must jettison its cumbersome requirements process, not the least of which involves excessive administrative layers and management oversight: plan, prebrief, brief, replan, rebrief, review, prebrief, brief, higher-level oversight/input, brief, changes, and more briefs.[41] Radical change is needed to strip the process of the many opportunities bureaucrats possess to insert themselves between program managers and program or weapon system delivery. The size and role of the OSD should shrink and return to policy and guidance. This notion entails eliminating redundancy in OSD acquisition offices. At a minimum have either the services or the OSD perform tasks that are currently duplicated. There is no need for both to go through the same decision processes. This change could accompany infusion of a "succeed quickly or fail fast" mentality. While such changes require managing risks, oversight is meant to mitigate risks; however, the historic growth of layered oversight has smothered discerning risk trade-offs. The entire process could be better performed by the services or program execution officers (PEO) rather than the OSD.

One further doctrinal change concerns budget stability. While many recommendations could be expounded upon here, suffice it to say, better planning around annual continuing resolution authority would help. However, given chronic underexecution of multiyear funds already in the possession of program offices, the budget is more often a scapegoat for underperformance than its cause. The real challenge here is to deliver on programmatics to create credibility in engaging the legislative branch to make changes that promote budget stability. The DOD could make significant progress here by adopting program performance (EVM-connected) metrics to replace the current, sole focus on percentage of budget spent. The DOD could undertake to work with Congress, since the latter wants better acquisition results too. If the DOD shows progress, Congress will help. Making honest calls—supported by real analytics, based on transparent assumptions, and promoted by experientially fortified leaders—would increase credibility and foster program successes. The DOD could build rapport with Congress by demonstrating successes, building on earned credibility to gain dispensations, changes, and wider latitude. Follow-through is essential, but careful cooperation and negotiation with Congress can produce advancement for the weapons acquisition community.

Organizational changes are certainly necessary—but not with a focus on the boxes in the wiring diagram. Within the structure, the DOD needs less oversight, more decision-making authority at lower levels, and increased accountability at *all* levels.[42] To ensure a disciplined process is used to identify, introduce, filter extraneous input, and employ technology, the PEO organizational structure should include a risk-management function. Currently, program managers are allowed to self-assess their risks—thus, producing a subjective, noncalibrated risk matrix that is only as good as the words used to "sell" the assessment, usually to an inattentive or technically uninformed audience. No objective, cross-organizational risk assessment is produced for the PEO, to say nothing of risk management at the service level or across all DOD Major Defense Acquisition Programs/Major Automated Information Systems or lower-level acquisition category programs. A risk-management function within the services would serve to inform with respect to the disparity between various program managers' risk tolerances and calibrate risk factors across programs. Fortune 500 firms have strategic risk-management offices, managing strategic corporate risks with respect to normalized risk appetite across the company's operating and compliance areas. Additionally, the software-certification organizations need to be answerable for arbitrary decisions that cripple simple, straightforward solutions. The one-size-fits-all approach is not just systematic of software-certification requirements but also applies to much of the acquisition process. While DOD officials talk about what needs to be done, seldom is resolute action taken. The current review and reform efforts championed by Congressman Mac Thornberry (R-TX) show promise, as they are exploring root causes.[43] A great first step would be to heed the old legal admonition that "good cases make bad law." To that end, statutes and regulations that sprouted from problems with specific programs but not systemic to the acquisition community deserve elimination. The fundamental shift required for the DOD is to reward the people who come forward to identify problems and save years of effort and funds. The current culture derides, if not outright punishes as naysayers, personnel who point out obstacles and often implies that such employees are disloyal to the program, the service, and the country.[44] Thus, very few people, and virtually no one with perceived gravitas, comes forward to dispel rampant optimism. In fact, gravitas is often bestowed upon those who speak from the script. Joined by an interested Congress, the

DOD may make progress toward needed reforms, but history suggests a certain amount of skepticism. Again, much anticipation is accorded Congressman Thornberry's indication that we are going to do reform different this time.[45] The most basic and influential reforms require Congress and the DOD to undo the misaligned incentives and refocus laws and regulations to inspire free-market behavior.

Conclusion

No matter where we start or which process we touch first, no doubt exists that the defense acquisition community needs reform. At the tactical and operational levels, we can look at things like software and program management accountability. But, we must not confuse symptom treatment as a cure. The disease within defense acquisition has metastasized across the tactical, operational, and strategic levels.

To produce effective and lasting reform, technological developments must be identified, as they are in the private sector, and leveraged to produce value-added results. The DOD must transition to a strict use of analytics and refine its strategic acquisition view, doctrine, and culture. After the strategic nature of the defense market is understood, a host of statutory and regulatory changes are required to shift from a socialistic approach to capitalistic incentives. Afterward, the DOD should build a new organizational structure around its acquisition efforts—a structure that enables decisions and solutions, not one that impedes progress. Among a multitude of other things, the DOD must change its understanding and approach to the defense economy and the number of programs pursued. Those two changes will create conditions that logically move the horde of other needed reforms.

In accomplishing acquisition reform, lessons from the biotech industry could be applied to the DOD as a prescription for what ails it. The application of innovative technology, relentless pursuit of the science, and a willingness to yield to facts distinguishes the biotech industry from defense. Strict adherence to the results of science versus bowing to dogma or predetermined concepts reveals the magnitude of what can be accomplished. As with private industry, the DOD should face facts, admit truths, and embrace radical change. Despite what many may think, businesses confront life and death challenges too, and their methods are applicable to weapons acquisition. **SSQ**

Notes

1. To expropriate a phrase, the history of acquisition reform might better resonate as "delusional repetition of discredited mistakes." David Brin, *Existence* (New York: Tor, 2012), 385. This is a result of failing to recognize the brutal facts comprising defense acquisitions.

2. J. Ronald Fox, *Defense Acquisition Reform, 1960–2009: An Elusive Goal* (Washington, DC: Center of Military History, United States Army, 2011), 78–79.

3. The de jure organizational structure within the acquisition community is clear-ish, but the de facto structure realizes the influence of user commands and other interested parties. Program managers must please multiple bosses.

4. The singular visual example of the complexity, indeed iconic within the acquisition community, is the wall chart depicting the "Integrated Defense Acquisition, Technology, and Logistics Life Cycle Management System." See http://www.public.navy.mil/spawar/PEOC4I /ASPG/Documents/APSG_Manuals/files/Integrated_Def_Acq_Management_Frmwk.pdf.

5. The McCain provisions incorporated into the fiscal year 2016 National Defense Authorization Act, while well intentioned, are likely to add another layer of bureaucracy. Giving the service chiefs a formal role, without removing the service secretary's role, will not reduce bureaucracy but exacerbate and grow it inside the services, much like it is duplicative between the services and the OSD.

6. William J. Perry, former secretary of defense, interview with the author, Stanford University, 3 February 2014.

7. Department of Defense Instruction (interim) Number 5000.02, 26 November 2013. The terms "tailor," "tailored," and "tailoring" appear in this document no less than 41 times. Tailoring of milestones, decision points, and phases is defined as milestone decision authorities (MDA), having full latitude to adapt programs in the most effective and efficient structure as much as needed to accommodate the characteristics of the product being acquired and to the totality of circumstances associated with the program—including operational urgency and risk factors.

8. James C. Collins, *Good to Great: Why Some Companies Make the Leap—and Others Don't* (New York: HarperCollins, 2001).

9. Frank Kendall quoted in, David Martin, "F-35: Looking at Most Expensive Weapons System Ever," *60 Minutes*, 16 February 2014, http://www.cbsnews.com/news/f-35-looking-at -most-expensive-weapons-system-ever/.

10. The success of long-term initiatives hinges on CEO tenure. Much has been written about DOD senior leadership turnover and the lack of traction gained by their reform attempts. "Fire and forget" or "implement and exit" are not viable strategies for fundamental reform.

11. Confrontation is pervasive between the OSD and services' program offices and descriptive of the DOD's relationship with Congress.

12. Héctor Hernández, Alexander Tübke, Fernando Hervás Soriano, Antonio Vezzani, Sara Amoroso, Mafini Dosso, et al. *The 2013 EU Industrial R&D Investment Scorecard* (Seville, Spain: Joint Research Centre, European Commission, 2013), 42.

13. Martin Zwilling, "10 Ways for Startups to Survive the Valley of Death," *Forbes*, 18 February 2013, http://www.forbes.com/sites/martinzwilling/2013/02/18/10-ways-for-startups -to-survive-the-valley-of-death/.

14. Gordon Binder and Philip Bashe, *Science Lessons: What the Business of Biotech Taught Me about Management* (Boston, MA: Harvard Business Press, 2008), 171.

15. "Be Science-Based" is the Amgen value with primacy of place, supporting the mission "To Serve Patients." See Amgen, "Mission and Values," 2015, http://wwwext.amgen.com/about /mission_values.html.

16. This notion is also prevalent in IT device, data, and services companies like Microsoft, Google, and Amazon, as well as innovation firms such as SRI International and 3M.

17. Binderand Bashe, *Science Lessons*, 203.

18. Fareed Zakaria, "Why Defense Spending Should Be Cut," *Washington Post*, 3 August 2011, 7; and J. Ronald Fox, *Defense Acquisition Reform, 1960–2009: An Elusive Goal* (Washington, DC: Center of Military History, United States Army, 2011), 207.

19. Ibid., 193.

20. Given references to the current DOD agencies as the fourth estate, I submit major defense contractors comprise the fifth estate.

21. Boeing is the "one" meant here, as it is the one major defense firm that most people reference when the subject of dual-use production arises. However, even this one is tenuous, as the Boeing Defense Group is far removed legally from the Boeing Company's commercial product lines. For a discussion of dual-use concerns, see Richard A. Bitzinger, ed., *The Modern Defense Industry: Political, Economic, and Technological Issues* (Santa Barbara, CA: Greenwood Publishing Group, 2009), 132–37.

22. Cynthia Robbins-Roth, *From Alchemy to IPO: The Business of Biotechnology* (Cambridge, MA: Perseus Publishing, 2000), 16.

23. The current buzzword is *innovation*. Little evidence exists to suggest the use of the word by the DOD hierarchy is anything more than a substitute for *transformation* or merely a collection of good ideas and best practices. *Innovation* entails a radical departure from the status quo—a combining of technologies to produce existing products in a new way or to create something entirely new. The essence of innovation—the "new"—is value creation. To embrace innovation means to become more like 3M, Amgen, SRI International, Google, Amazon, Apple, and so forth. Innovation requires allowances for creative thinking, freedom of action, and multidisciplinary/cross-industry collaboration.

24. Usually, momentous changes to the DOD result from "burning platforms." The last major reform, while not aimed at or the result of acquisitions per se, was a burning platform. The fireball that ended the Iranian hostage rescue attempt in the desert outside Tehran produced the Goldwater–Nichols Defense Reorganization Act six years later.

25. DOD purchasing power is not to return. Even if sequestration is repealed and defense budgets again climb upward, the national fiscal crises can only be averted by inflationary policies that erode the value of the debt and associated government unfunded liabilities, which, by conservative estimates, exceed $75 trillion. Thus, any restored defense budgets will provide near zero or negative real purchasing power.

26. An interesting word choice as biologically *transformation* is what a cell does when it becomes cancerous. More accurately, transformation is the process for converting normal cells into tumor cells. Brent R. Stockwell, *The Quest for the Cure: The Science and Stories behind the Next Generation of Medicines* (New York: Columbia University Press, 2011), 85.

27. Napoleon Bonaparte dramatically changed the way war was fought, but he did not drive the technology component of that era's transformation. He took advantage of the innovations in firepower technology by changing the fighting doctrine and organizational structure within the Grand Armée. However, he did not create all aspects of the transformation. He merely possessed the genius, lacking in others, to discern what the change in technology offered and capitalized upon it to his advantage.

28. Air Command and Staff College, "Strategy and War" course, Maxwell AFB, AL, October 2005. See also, Thomas C. Hone and Norman Friedman "Harnessing New Technologies," in *Transforming America's Military*, edited by Hans Binnendijk (Washington, DC: National Defense University Press, 2002), 31.

29. Note the application of John Boyd's famous OODA loop: observe, orient, decide, and act. Quick action is required to leverage change; this notion is not unrelated to an oft repeated business mantra: innovate or die!

30. Daniel Ward, *Changing Acquisition Culture: What and How* (Washington, DC: Center for National Policy, November 2013), 5, http://cnponline.org/p/changing-acquisition-culture/.

31. P. W. Singer, *Wired for War: The Robotics Revolution and Conflict in the Twenty-First Century* (New York: Penguin Books, 2009), 46.

32. Ibid., 56.

33. Mark A. Lorell, Michael Kennedy, Robert S. Leonard, Kenneth Munson, Shmuel Abramzon, David L. An, and Robert A Guffey, *Do Joint Fighter Programs Save Money?* (Santa Monica, CA: RAND Corporation, 2013), 39.

34. Word choice is far less significant than attaining meaningful change on cost, schedule, and performance, which all increase user value. A cheaper process allows transfer of funds for operational needs or a shortened upgrade cycle; faster process puts capability in war fighters' hands sooner; and performance of requirements is user value.

35. Department of Defense Authorization Act, 1983, Pub. L. No. 97-252, 10 U.S.C. § 2433 (8 September 1982). This law is also known as the Nunn–McCurdy Act for the principle sponsors of an amendment thereto requiring the DOD to report to Congress whenever a major defense acquisition program experiences cost overruns that exceed certain thresholds. Readers can find an online version at Cornell University's Legal Information Institute's website at https://www.law.cornell.edu/topn/department_of_defense_authorization_act_1983.

36. The DOD argument against business practices is the absence of a profit motive. The line goes something like this: "We can't do that because we don't have the ultimate measure of profit." The DOD could effectively use lethality as a measure for decisions. If a project or activity does not increase battlefield lethality, we should look very hard at it. Treat lethality as a proxy for profit. This substitution permits free-enterprise, decision-making analysis inside the DOD.

37. David Martin, "F-35: Looking at Most Expensive Weapons System Ever."

38. Fox, *Defense Acquisition Reform*, 37, 55, and 178. These pages address concurrency failures in the 1960s that later became acquisition policy recommendations in the late 1980s.

39. Once asked by a general officer why DTS did not work like TurboTax®, I responded that, if Intuit built it instead of a defense contractor, it would. However, that would require the DOD to possess the expertise to properly define its requirements and accept the bid of software experts, rather than accepting lower bids from firms that know the buy-in game and are willing to work on something for decades. This also hints to the problem of progress payments on schedules.

40. Ward, *Changing Acquisition Culture*, 1.

41. A PEO, who will remain anonymous, initiated a review of the administrative requirements associated with delivering a program. Findings indicated that three years of planning, approvals, documentation, and briefings were required on programs. Interestingly, the DOD wants program delivery in those same three years. The administrative burden outside of coding a single line of software or bending the first piece of sheet metal consumed the entirety of the desired acquisition timeframe.

42. The best way to accomplish this is the wholesale abolishment of some boxes.

43. Steven P. Bucci and Emil Maine, "Thornberry Initiative for Effective Defense Acquisition Reform Appears Promising." *Issue Brief* (Heritage Foundation), no. 4106, 12 December 2013, http://www.heritage.org/research/reports/2013/12/thornberry-initiative-to-reform-the-defense-acquisition-process.

44. Such disciplinary action is not manifested as overt punishment but in loss of regard with respect to the programmatics, in meetings, or among the group and a lack of recognition or promotion.

45. Mac Thornberry, Congressman (R-TX), interviewed by Vago Muradian, *This Week in Defense News*, 29 January 2013. Available online at "Rep. Thornberry Interviewed on This Week in Defense News," *YouTube*, 29 January 2013, http://www.youtube.com/watch?v=bXpH7lEdyO0.

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